Supreme Court, U.S.
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08-584

No. ____

In The
Supreme Court of the United States

CARETOLIVE, A NOT FOR PROFIT CORPORATION
C/O STATUTORY AGENT,

Petitioner,

v.

ANDREW VON ESCHENBACH, OFFICIAL CAPACITY AS
COMMISSIONER FOOD AND DRUG ADMINISTRATION,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Sixth Circuit

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PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

1) Is the "final agency action" requirement as set forth in the Administrative Procedures Act (APA) a *jurisdictional requirement* so as to allow the Court to summarily dismiss Plaintiff's Complaint on jurisdictional grounds under Civil Rule of Procedure 12(b)(1), without further pleading, without review of the administrative record and without any discovery on that issue?

RULE 14.1(b) STATEMENT

A list of all parties to the proceedings in the court whose judgment is the subject of this petition is as follows:

Petitioner: CareToLive, a not for profit corporation.

Respondent: Andrew von Eschenbach, in his capacity as commissioner of the Food and Drug Administration.

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PETITION FOR A WRIT OF CERTIORARI

CareToLive respectfully petitions for a writ of certiorari to review the opinion and judgment of the U.S. Court of Appeals for the Sixth Circuit.

OPINIONS BELOW

The opinion of the U.S Court of Appeals for the Sixth Circuit, dated 8/28/08 is at http://www.ca6.uscourts.gov/opinions.pdf/08a0533n-06.pdf. Slip Copy, 2008 WL 3983950, (Not Selected for publication in the Federal Reporter), C.A.6 (Ohio), August 28, 2008 (NO. 07-4465).

The site to the decision of the District Court for the Southern District of Ohio, Eastern Division is *CareToLive vs. von Eschenbach,* 525 F.Supp.2d 938, S.D. Ohio, November 21, 2007 (NO. 2:07-CV-729).

JURISDICTION

The judgment of the U.S. Court of Appeals for the Sixth Circuit sought to be reviewed was entered on August 28, 2008. This petition is timely under 28 U.S.C. § 2101(c) and Supreme Court Rule 13.1 because it is being filed within 90 days of the entry of the opinion and judgment sought to be reviewed. This Court has jurisdiction to review the judgment of the U.S. Court of Appeals for the Sixth Circuit pursuant to 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

The relevant statutory provision involved is 5 U.S.C. § 702 and 704.

STATEMENT OF THE CASE

This action arises out of the May 8, 2007 denial by the Food and Drug administration of a Biologics License Application BLA to Dendreon Corporation, a Seattle based biotechnology company who seeks to distribute an immunotherapy called Provenge to late stage prostate cancer patients who have no viable treatment options.

CareToLive is a non profit advocacy group that has as members: doctors including oncologists, nurses, investors, prostate cancer patients, families of patients, advocates of patients (individuals and groups) and other concerned citizens. On behalf of its members and the citizens of this Country they seek transparency and accountability from a Federal Agency that has refused to account for the method utilized for review of the BLA and/or reasoning for ignoring its 17 member hand picked panel of experts, who recommended the granting of the BLA for Provenge.

In recognition that safe, effective treatments were taking too long to get to patients who have serious life threatening conditions such as cancer, Congress enacted legislation designed to get treatments to the patients in a more timely manner. First, a Biologics License Application (BLA) can receive Fast Track Status. Later in the process, if there are sufficient

data, a BLA can be granted "Priority Review Status". When Priority Review is granted, the Prescription Drug User Fee Act ("PDUFA") date, which is the date the FDA must return their decision on the BLA, is 6 months from the date the completed application was submitted by the applicant.

Products regulated by FDA's CBER division are eligible for priority review if they provide a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious or life-threatening disease. Products are not generally granted Priority Review (and presented to an Advisory Committee ("AC") if there are *insufficient data*.

Both the clinical and non clinical sections of the Provenge rolling submission were completed and provided to the FDA as of August 24, 2006. The chemistry manufacturing and controls sections submitted in November 2006 completed the application process. The Rolling Review allows the FDA clinicians to review the sections of the data as it comes in and work with the applicant to make sure that they have the proper and required data, rather than waiting to begin their review only after the entire BLA has been submitted.

Between August 24th, 2006 and the issuance of the Complete Response (CR) Letter on May 8th 2007, which denied a BLA for Provenge, the FDA actions were contrary to the later assertion that the data were not sufficient to be able to evaluate the safety or efficacy of Provenge. The FDA does not empanel Advisory Committees if there are insufficient data for the experts to make an evaluation. After years of review of

the rolling submission and then clinical review of the final application submitted on November 15, 2006, the FDA approved the application for filing and assigned it priority review status on January 16, 2007.

The Provenge BLA, having been completely submitted on November 15, 2006 and having been granted Priority Review, the decision date by which the FDA had to *act* in the case of Provenge, was May 15, 2007. When the FDA accepted the Provenge application and granted Priority Review status to the application, it did so because FDA clinicians determined that there were in fact sufficient data, and because Provenge is a treatment for a life threatening condition for which there are no viable treatment options.

Once the application was accepted rather than "refused to file", the options available to the FDA were to approve, to not approve, or to grant conditional approval. Asking for "more data" after more than 9 months of review, after submission to an expert panel of 17 committee members hand picked by the FDA to review the application (at the advisory committee meeting), is essentially stating that the application was incomplete, something more reasonably determined before accepting the BLA and before convening the AC and thus before wasting millions of dollars. At the public meeting none of the Expert AC members stated they needed more data to evaluate the Provenge BLA.

The convening of outside AC panels is *extremely* expensive for both the applicant and the FDA. This case is a perfect example of an unmet medical need,

Fast-tracked given Priority Review status and approved by the AC, all as per the Congressional mandate, but then delayed for improper reasons, thereby achieving the opposite of the mandate to speed treatments along to patients, and instead stalling and resetting the clock in backwards motion, thereby delaying an effective, safe therapy for countless years on end.

The record is fully established. We even have had a hearing judged by handpicked outside experts followed by an FDA decision in contravention of the expert panel's opinion, without explanation. Rights to access have been decided and denied. The Citizenry has been denied transparency and accountability as to this decision by the FDA.

This case is unprecedented in that the patients herein are missing out on a treatment that:

1. Has been through over a decade of testing,
2. has proceeded through phase one, phase two, and two phase three trials, all under the guidance of the FDA,
3. has since, partially completed a fourth (additional expanded third) phase three trial and demonstrated significant survival benefit according to an Independent Data Monitoring Company (IDMC),
4. has been reviewed by FDA clinicians and determined to be worthy of Fast Track Status,
5. was then again reviewed by FDA clinicians and determined to be worthy of Priority Review Status,

6. has been granted a hearing overseen by a panel of 17 outside experts hand picked by the FDA,
7. has had an expert panel find overwhelmingly that it is safe and that it has demonstrated substantial evidence of efficacy (the Congressionally mandated standard),
8. which is a treatment for a late stage prostate cancer (AIPC) patient class.

The results of that Advisory Committee hearing on Provenge, was that the experts voted 17 to 0 that Provenge was safe. The panel also voted by a vote of 13 to 4 that there was substantial evidence of efficacy.

Despite the public perception and expectation that the FDA would follow the advice of the expert committee that was convened and voted at the AC hearing, on May 8, 2007, the FDA shockingly issued a Complete Response Letter (CR) to Dendreon announcing that they were not going to approve Provenge but instead would like additional data (as recommended to them, post AC, by the two "no" voting committee members who obtained conflict of interest waivers but were later shown to have other unreported conflicts). Since then an IDMC announced that Provenge showed survival benefit on an interim basis in the ongoing new phase three trial, a very difficult achievement in a drug trial at interim, particularly one where there is considerable evidence that the immunotherapy takes time to ramp up and best perform.

The FDA did one thing in public and acted another way in private. There is a lack of transparency in the FDA so exactly how they reached the decision to ignore

the expert panel and not approve Provenge, is mostly unknown. The public including doctors and their patients, only see the public face that the FDA has placed on Provenge. The FDA operates in the back rooms with virtually no oversight. The FDA owes a duty to the public they are sworn to serve, to provide a rationale for their decision to deny approval to Provenge, something they have to date refused to do.

Without further pleading and without any discovery or requested hearings or any review of the administrative record, the District Court dismissed the Plaintiff's Complaint which sought a review of the due process afforded the BLA and some transparency and accountability from the FDA for the watching world. The Sixth Circuit Court of Appeals denied the Appellants appeal and affirmed the decision of the District Court without written decision, merely adopting the decision of the District Court.

The District Court wrongfully dismissed Plaintiff's Complaint on the basis that it did not have jurisdiction to decide the matter under 12(b)(1).

REASONS FOR GRANTING THIS PETITION

The District Court was wrong to dismiss the Plaintiff's Complaint on jurisdictional grounds. The District Court was mistaken when it interpreted the Administrative Procedures Act (APA) "final agency action" requirement" as jurisdictional. The decision is contrary to and thus conflicts with the case law from the D.C Circuit.

This Court should grant Certiorari to address the now conflicting case law between the Sixth Circuit and the D.C. Circuit Courts.

I. THE SIXTH CIRCUIT'S DECISION AFFIRMING THE DISTRICT COURT DECISION TO DISMISS PLAINTIFF'S COMPLAINT ON JURISDICTIONAL GROUNDS, IS IN CONFLICT WITH THE D.C. CIRCUIT AND CONTRARY TO THIS COURTS STATEMENTS REGARDING DISMISSAL ON JURISDICTIONAL GROUNDS.

An action under 5 U.S.C. § 702 and § 704 known as the Administrative Procedures Act (APA) takes final agency action. However final agency action is not a jurisdictional requirement and thus the factual disputes regarding that issue are subject to; further pleading, a different burden of proof, and some discovery, all of which the lower Court denied. Some of the transparency and accountability sought as relief by the Plaintiff in the Complaint would actually have been achieved by the mere imposition of the requirement that the Defendant in this matter be required to properly file an answer to the Plaintiff's Complaint. Importantly, the District Court should also review the administrative record before deciding the issue of "final agency action" and dismissing a case on jurisdictional grounds. If the lower Court had decided the matter alternatively under Civil Rule 12(b)(6) it would have had to accept all the factual contentions of Plaintiff as true. The Court also failed to consider that "failure to act" in a timely manner could also be a basis to proceed under the APA.

The District Court dismissed under Civil Rule 12(b)(1) on jurisdictional grounds but the Plaintiff has a right to conduct some limited discovery on the issue of final agency action. Discovery may be appropriate regarding jurisdictional challenges and the issue of final agency action is a factual question entitling Plaintiffs to discovery. *Center For Biological Diversity v. U.S. Dep't of Housing and Urban Dev.*, 241 F.R.D. 495, 501 (D.Ariz., 2006). Importantly the Sixth Circuit decision in the instant case is in conflict with *Trudeau v. FTC*, 456 F.3d 178, 184 (D.C.Cir.2006) which stated that "the APA's final agency action requirement is not jurisdictional". See 5 U.S.C. § 702 (authorizing judicial review of "agency action").

While it is true that some opinions have loosely referred to the final agency action requirement as "jurisdictional, that is hardly surprising, as jurisdiction ... is a word of many, too many, meanings.'" *Arbaugh v. Y & H Corp.*, 546 U.S. 500, 126 S.Ct. 1235, 1242, 163 L.Ed.2d 1097 (2006) (quoting *Steel Co. v. Citizens for Better Environment*, 523 U.S. 83, 90, 118 S.Ct. 1003, 140 L.Ed.2d 210 (1998)). Or, as Judge Friendly and Justice Frankfurter put it more poetically, the word is "a verbal coat of too many colors." *In re Beck Indus., Inc.*, 725 F.2d 880, 881 (2d Cir.1984) (Friendly, J.) (quoting *United States v. L.A. Tucker Truck Lines, Inc.*, 344 U.S. 33, 39, 73 S.Ct. 67, 97 L.Ed. 54 (1952) (Frankfurter, J., dissenting)). In the case of *Reliable Automatic Sprinkler Co. v. Consumer Prod. Safety Comm'n*, the D.C. Circuit Court made clear that, where "judicial review is sought under the APA rather than a particular statute prescribing judicial review, the requirement of final agency action is *not* jurisdictional." 324 F.3d 726, 731 (D.C.Cir.2003).

In another case, recently decided, the D.C. Circuit Court followed *Reliable,* reaffirming that the APA's final agency action requirement is not jurisdictional. *Center for Auto Safety v. NHTSA,* 452 F.3d 798, 805 (D.C.Cir.2006) (citing *Reliable,* 324 F.3d. at 731). *Trudeau v. Federal Trade Com'n* 456 F.3d 178, 184, 372 U.S.App.D.C. 335, 341 (C.A.D.C., 2006). The Court in Trudeau stated:

> In sum, we hold that APA § 702's waiver of sovereign immunity permits not only Trudeau's APA cause of action, but his nonstatutory and First Amendment actions as well. We also hold that the waiver applies regardless of whether the FTC's press release constitutes "final agency action." *Accord Presbyterian Church (U.S.A.) v. United States,* 870 F.2d 518, 525 (9th Cir.1989) (holding that the government's "attempt to restrict the waiver of sovereign immunity to actions challenging 'agency action' as technically defined in § 551(13) offends the plain meaning of the amendment"); *Red Lake Band of Chippewa Indians v. Barlow,* 846 F.2d 474, 476 (8th Cir.1988) (rejecting the contention that the waiver in § 702 "exists only to allow review of a final agency decision," and holding that "[t]he waiver of sovereign immunity contained in section 702 is not dependent on application of the ... review standards of the APA"). The district court therefore had subject-matter jurisdiction to hear Trudeau's suit under 28 U.S.C. § 1331, and its *dismissal of the complaint for lack of jurisdiction pursuant to Rule 12(b)(1) was erroneous.* (emphasis added)

The lower Court erroneously dismissed this matter on the basis of lack of jurisdiction under 12(b)(1). The District Court accepted unsupported factual contentions of the Defendants without having accepted the Plaintiffs factual contentions, and did this without allowing any discovery and without review of the Administrative Record, then dismissed the action on jurisdictional grounds. Upon adoption by the Sixth Circuit of that decision it is now in conflict with the D.C. Circuit Court decisions. The use of "jurisdiction" as a verbal coat of this color must be discouraged as previously stated by this Court and this is an exceptionally important issue as it will insure that Courts do not continue to erroneously dismiss cases brought under the APA on jurisdictional grounds.

CONCLUSION

The petition for the writ of certiorari should be granted.

Respectfully submitted,

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